IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

JERRY BODIE;

Plaintiff,

v.

THE PURDUE PHARMA COMPANY;
PURDUE PHARMA L.P.;
PURDUE PHARMA INC.;
PURDUE FREDERICK COMPANY;
THE P.F. LABORATORIES, INC.;
ABBOTT LABORATORIES;
ABBOTT LABORATORIES, INC.;

Defendants.

CV-02-C-2838-W

COMPLAINT

COMES NOW the Plaintiff, Jerry Bodie by and through counsel, and for his Complaint against the Defendants states the following upon information and belief:

PARTIES

1. Plaintiff, Jerry Bodie, is a resident citizen of Tuscaloosa County, Alabama. Plaintiff was prescribed and did ingest OxyContin marketed, distributed, packaged, promoted, prescribed and/or sold by the Defendants, and suffered permanent injury as a result. Plaintiff is and was a resident of Alabama at all times relevant to this cause of action.

2. The Purdue Pharma Company is a general partnership organized and existing under the laws of the State of Delaware with its principal place of business at 100 Connecticut Avenue, Norwalk, Connecticut. The Purdue Pharma Company owns the patent for OxyContin Tablets and, upon information and belief, was, at all times relevant hereto, in the business of

designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin directly or indirectly, to persons throughout Alabama.

3. Defendant Purdue Pharma L.P. is a Delaware limited partnership with its principal place of business located at One Stamford Forum, Stamford, Connecticut. At all times relevant hereto, Purdue Pharma L.P. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin® throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama.

4. Defendant Purdue Pharma Inc. is a Delaware corporation with its principal place of business located at One Stamford Forum, Stamford, Connecticut. At all times relevant hereto, Purdue Pharma Inc. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama. Purdue Pharma Inc. is the general partner of Purdue Pharma, L.P., and at all relevant times supervised and managed the operations and affairs of its subsidiary and affiliate, Purdue Pharma, L.P.

5. Defendant The Purdue Frederick Company is a New York corporation with its principal place of business located at 100 Connecticut Avenue, Norwalk, Connecticut. At all times relevant hereto, The Purdue Frederick Company was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama.

6. Defendant The P.F. Laboratories, Inc. is a New Jersey corporation with its principal place of business located at Totowa, New Jersey. At all times relevant hereto, The P.F. Laboratories, Inc. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama.

7. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business located at Abbott Park, North Chicago, Illinois. At all times relevant hereto, Abbott was in the business of advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama. At all times relevant hereto Abbott Laboratories supervised and managed the operations and affairs of its affiliate and subsidiary, Abbott Laboratories, Inc.

8. Defendant Abbott Laboratories, Inc., is a Delaware corporation with its principal place of business located at Abbott Park, North Chicago, Illinois. At all times relevant hereto, Abbott Laboratories, Inc., was in the business of advertising, promoting, marketing, selling and/or distributing OxyContin throughout the State of Alabama, and its actions have affected commerce within this county and the State of Alabama.

9. At all times complained of herein, The Purdue Pharma Company, Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, and The P.F. Laboratories, Inc., ("Purdue") and Abbott Laboratories, and Abbott Laboratories, Inc. ("Abbott")(collectively referred to as the "Pharmaceutical Defendants") were acting for and on their own behalf and as agents, ostensible agents, servants and/or employees, of one another, in the course and

scope of their employment, agency and/or ostensible agency.

10. At all times complained of herein, the Pharmaceutical Defendants were acting as conspirators, one with the other, and with unnamed persons, firms and corporations in common goals, schemes and designs for the goals and purposes as herein alleged and complained of.

11. At all times complained of herein, all Defendants entered into a joint venture, one with the other, and with unnamed persons, firms and corporations for the goals and purposes as herein alleged and complained of.

JURISDICTION AND VENUE

12. Subject matter jurisdiction is proper in this Court pursuant 12 U.S.C. § 1392, as the parties are diverse and the amount in controversy exceeds $75,000. As a result of the manufacture, distribution, marketing, promotion, delivery and sale of OxyContin to consumers, including Plaintiff, within Tuscaloosa County and throughout the State of Alabama, Defendants, directly or through their subsidiaries, affiliates or agents, obtained the benefits of the laws of the State of Alabama and the Alabama market for painkillers.

13. Venue is proper in the district in that a substantial part of the acts or omissions giving rise to this action occurred in this district.

FACTS

14. OxyContin is an opioid analgesic drug, sold in tablet form, containing oxycodone hydrochloride. As with other opioids, oxycodone users may become addicted to the drug upon repeated administration.

15. The Food and Drug Administration ("FDA") approved OxyContin for sale in 1995. The drug's original indication was for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendant Purdue and its subsidiaries and affiliates patented, developed, manufacture, market, and distribute OxyContin. Defendant Abbott co-promotes OxyContin.

16. OxyContin was initially available in 10 mg, 20 mg, and 40 mg tablet strengths. In 1997, the Pharmaceutical Defendants introduced 80 mg tablets, and in July 2000, 160 mg tablets. The Pharmaceutical Defendants also planned to market a 240 mg tablet. The Pharmaceutical Defendants had to develop higher potency pills as a result of the natural progression of opioid tolerance in OxyContin users, and as explained below, the limited effectiveness of OxyContin.

17. OxyContin contains far more milligrams of oxycodone than any other oxycodone drugs on the market. For example, the 80 mg dosage of OxyContin contains as much oxycodone as sixteen Percocet pills.

18. The Pharmaceutical Defendants launched OxyContin in December 1995. Just four (4) years later, OxyContin ranked 36th in sales in the United States of all prescription medications, with total sales of $601,128,000 resulting from 3,505,000 prescriptions that year. Total sales of OxyContin surpassed $1 billion annually in the United States in 2000. The Pharmaceutical Defendants achieved these sales by (1) recklessly promoting OxyContin, an alleged long-acting, long-term potent opioid pain killer, for inappropriate uses [Part I(A), below,]; (2) misrepresenting to consumers that OxyContin tablets provided smooth and sustained 12-hour pain relief [Part I(B), below]; and (3) distorting and diminishing the safety

risks of OxyContin, including opioid dependence, tolerance, withdrawal, and addiction. [Part I(C), below.] The Pharmaceutical Defendants' actions proximately caused injuries to Plaintiff.

I. THE PHARMACEUTICAL DEFENDANTS

A. Overpromotion

19. The Pharmaceutical Defendants sought to increase the market share for their opioid pain killer by aggressively marketing and promoting OxyContin as having a lower abuse potential than other opiate pain relievers, and suggesting that physicians prescribe OxyContin as a substitute for a variety of less addicting existing medications.

20. The Pharmaceutical Defendants' overpromotion of OxyContin included overly aggressive detailing of doctors by sales representatives, seminars for doctors regarding pain management, the dissemination of inaccurate marketing materials, the giving away of gifts not related to the physician's work like beach-hats and compact discs. These activities and items did not adequately describe the defective nature or harmful side effects of OxyContin, and misrepresented OxyContin's ability to reliably provide 12-hour pain relief.

21. The American Medical Association, through the Council on Ethical and Judicial Affairs, issued 1990 and revised in 1998 ethical guidelines for gifts provided by pharmaceutical companies. Specifically "E-8.061: Gifts To Physicians from Industry" sets limitations as to what pharmaceutical companies can ethically give to physicians they wish to prescribe their drug. Specifically, E-8.061 states, in pertinent parts:

> . . . [T]here has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

1. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. . . .

2. Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

5. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

* * *

7. No gifts should be accepted if there are strings attached. . . .[1]

22. These guidelines are meant to prevent and deter coercive and inappropriate conduct of the pharmaceutical company representatives, which would unfairly and illegally influence the utilization of pharmaceutical company products.

23. Notwithstanding the AMA ethical guidelines, the Pharmaceutical Defendants, in an effort to influence their prescription of OxyContin, among other actions, paid doctors' transportation and hotel costs to attend weekend meetings to discuss pain management. At these company sponsored seminars, the Pharmaceutical Defendants recruited doctors and paid them fees to speak to other doctors to market OxyContin as a safe and effective way in which to treat all manner of pain, including minor pain, yet failed to provide accurate and adequate information related to the potential for addiction and for foreseeable abuse.

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[1]Issued June 1992 based on the report, "Gifts to Physicians from Industry," adopted December 1990; (JAMA. 1991; 265: 501 and Food and Drug Law Journal.1992; 47: 445-458); Updated June 1996 and June 1998.

24. In addition, and in contravention to E-8.061, the Pharmaceutical Defendants provided physicians individual gifts of minimal value that were not related to the physician's work, such as beach hats with "Q12h OXYCONTIN CII (OXYCODONE CONTROLLED RELEASE TABLETS)" stitched on the front. In addition, the Pharmaceutical Defendants also distributed to physicians serving elderly patients a compact disc containing music geared towards elderly patients. The compact disc was titled "Swing is Alive" with a promotional banner at the bottom of the cover "Swing in the right direction with OXYCONTIN®". The cover featured two senior citizens dancing. The banner highlighted the time release nature of OxyContin. The disc included artists such as: The Andrews Sisters, Les Brown, Duke Ellington, The Benny Goodman Orchestra, Jimmy Dorsey & his Orchestra, and Count Basie. Defendants specifically chose these artists to market OxyContin to elderly patients likely to be suffering from various painful conditions, including osteoarthritis.

25. The Pharmaceutical Defendants' sales representatives used highly coercive and inappropriate tactics to convince physicians and pharmacists to prescribe and fill OxyContin prescriptions, often when it was inappropriate. These sales representatives, also known as detailers, derived a significant commission on OxyContin sales. In their efforts to make money, detailers told physicians and pharmacists, among other things, that OxyContin "was safe enough to treat short-term pain"; that it was safer than non-steroidal, anti-inflammatory drugs such as Advil; that it should be prescribed to elderly patients with osteoarthritis; and that it should be prescribed for all pain relief needs. In addition, the Pharmaceutical Defendants and their detailers sought to intimidate doctors by exaggerating the impact of a jury verdict against a doctor for under-medicating the pain of a terminally ill cancer patient. As part of their sales script, detailers warned physicians that they could face multiple claims for medical malpractice or lawsuits if they did not prescribe OxyContin for pain management. Similarly, detailers told pharmacists that they could also suffer adverse legal consequences if they failed to fill OxyContin prescriptions, even if they believed the patient may be abusing the drug.

26. A Purdue spokesperson acknowledged that many of the thousands of sales representatives hired since the 1990's were unaware of the American Medical Association's ethics guidelines, which were created to deter coercive and inappropriate sales tactics. With their livelihoods at stake, and driven by commissions, the Pharmaceutical Defendants' sales representatives, under their directions, greatly expanded OxyContin's share in the pain management market, including in Mississippi.

27. The Pharmaceutical Defendants also finance an internet site called "Partners Against Pain," which promotes "time-release opioids" [i.e., OxyContin] to the public. "Partners Against Pain" also encourages patients to "doctor-shop" by advising patients to "never give up," and to "search" for a doctor who will give them the "new" time-release opioid for their pain.

28. Pharmaceutical Defendants were and are facilitating the inappropriate use of OxyContin by supplying pharmacies in Mexico with OxyContin, because they are aware that members of the public can obtain OxyContin from these pharmacies without a prescription.

29. On May 11, 2000, the United States Food and Drug Administration issued an official warning letter to Purdue ordering it to cease use of an advertisement for OxyContin. The ad stated and/or implied that OxyContin could be used to treat arthritis patients without first using milder drugs. The FDA letter stated:

> You present the headline, 'Proven Effective in Arthritis Pain' on the first page of the journal ad, followed by the results of a study conducted in 133 patients with moderate to severe osteoarthritis on the second page. This presentation suggests that OxyContin had been studied in all types of arthritis and can be used as first-line therapy for the treatment of osteoarthritis. . . . You should immediately discontinue the use of this journal advertisement and all other promotional materials for OxyContin that contain the same or similar claims or presentations.

Purdue later withdrew the advertisement in question.

30. Throughout their detailing and promotion of OxyContin, the Pharmaceutical Defendants ignored guidelines established by pain management experts, which direct the use of opioids, if at all, only after all other reasonable attempts at pain relief have failed, and to use caution or forego long-term opioid therapy for pain patients with a past history of substance abuse. Finally on July 18, 2001, the FDA forced the Pharmaceutical Defendants to revise the label for OxyContin to make clear that it was inappropriate as a first-line therapy for pain management, and as a "prn" or "as needed" drug.

31. Ultimately, the inappropriate use and abuse of OxyContin spurred by the Pharmaceutical Defendants' marketing practices grew to such a level that the Drug Enforcement Administration (DEA) asked Purdue to limit promotion of OxyContin only to doctors who specialize in the management of pain. This was the first time that the DEA

targeted a specific prescription drug to curb its misuse.

B. Misrepresentations of Efficacy; Design Defect

32. Pharmaceutical Defendants represent that OxyContin provides smooth, sustained, and sufficient pain relief when taken just twice a day. Twice-a-day dosing is often referred in medical parlance as BID [bi-daily], "qua 12 hours," or "q12h."

33. OxyContin does not provide sufficient pain relief for the majority of patients when dosed every 12 hours, and the Pharmaceutical Defendants knew that.

34. OxyContin consists of oxycodone hydrochloride mixed into a resin. The waxy resin is then pressed onto a plastic matrix. A portion of oxycodone resides in the tablet's outershell, to provide patients immediate relief. As the resin dissolves, oxycodone leaches through a layer of gel into the patient's stomach, and thereafter, into his or her blood stream. However, for OxyContin the gel layer formed is quite thin, thereby releasing nearly all of the oxycodone within the first few hours after administration.

35. The controlled-release feature of OxyContin fails to deliver a consistent and sufficient amount of oxycodone throughout the 12-hour dosing period. After several hours of OxyContin administration, clinically significant numbers of OxyContin patients again experience their underlying pain. OxyContin appears to "stop working" about six to eight hours of ingestion, and sometimes even sooner. In reaction to the limited effectiveness, the healthcare provider will often prescribe higher OxyContin dosages. The additional oxycodone, or additional rescue medications may temporarily tide patients over during the latter part of their 12-hour dosage interval, but the added oxycodone further develops the pain patients' tolerance. Patients who take OxyContin continuously, as per its indication, will

become physically dependent to oxycodone in as soon as a few days to two weeks. Increased tolerance requires pain patients to increase their oxycodone dosage, if not to dull their underlying pain, then to quell the pain associated with opioid withdrawal. Due to the Pharmaceutical Defendants' defective design of OxyContin, and their misrepresentations of its controlled-release feature, a majority of OxyContin patients will have inadequate oxycodone blood levels to relieve their pain and/or stave off opioid withdrawal symptoms during the latter part of their 12-hour dosing interval.

36. The Pharmaceutical Defendants knew, based on their own studies, that OxyContin does not provide consistent and sufficient pain control for a majority of patients when taken twice a day. In the Pharmaceutical Defendants' clinical trials, many study patients dropped out if the use of rescue medications was not permitted. In one OxyContin study, more than half the patients required rescue medications on greater than 75% of the study days; only 5% did not require any rescue medication. Other studies similarly demonstrated that OxyContin users required extensive use of rescue medication, or remedication, within the 12-hour dosing period.

37. The Pharmaceutical Defendants also knew that patients taking OxyContin as directed, for several days, around-the-clock, would quickly build up a tolerance to oxycodone. Combined with the shortcomings of OxyContin's controlled-release feature, OxyContin patients, like Plaintiff, would need frequent dosage increases to obtain pain relief, and stave off withdrawal. As with the Plaintiff here, the taking of higher OxyContin dosages led to higher tolerance, which led to the prescription of even higher dosages just to maintain some semblance of pain relief and to stave off opioid withdrawal symptoms.

38. In anticipation of OxyContin's limited efficacy, Purdue developed and launched immediate release oxycodone products. In 1996, Purdue introduced OxyIR [5mg oxycodone] and OxyFast [20 ml oxycodone liquid]. Purdue thereafter marketed OxyIR as "rescue medication" physicians should prescribe along with OxyContin. Pain patients inadequately relieved by OxyContin would now regularly purchase and consume these "rescue medications," on nearly a daily basis. The continual need for rescue opioids contradict the representations made by the Pharmaceutical Defendants that OxyContin offers all-day pain relief when taken just twice daily.

39. The Pharmaceutical Defendants have always misrepresented OxyContin's ability to provide 12-hour pain relief. In announcing the launch of OxyContin, Defendant Purdue proclaimed in a press-release that OxyContin presented a "significant advance" because "unlike short-acting pain medications, which must be taken every 3 to 6 hours – often on as 'as needed basis' – OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night." According to Paul D. Goldenheim, M.D., Vice President of Purdue Pharma, L.P.: "The importance of pain control with twice-daily dosing can't be stressed strongly enough . . . until now, patients with persistent pain had to take products ...as often as six times a day. Now with every twelve-hour OxyContin dose, many patients may experience pain relief and may enjoy daytime activities and nighttime rest without the inconvenience of taking tablets every four to six hours." To further underscore the misleading impression as to OxyContin's controlled-release feature, the press-release further noted that the clinical studies of OxyContin found "12 hours of smooth and sustained pain control were provided by OxyContin tablets." That statement is false, as OxyContin does not

provide a smooth or sustained release of oxycodone, and fails to reliably provide smooth and sustained pain relief when taken twice daily.

40. The OxyContin Package Insert created by the Pharmaceutical Defendants misrepresents that OxyContin provides 12-hour pain relief when taken twice a day. The insert states that "OxyContin Tablets are designed to provide controlled delivery of oxycodone over 12 hours," and that, "[t]he controlled-release nature of the formulation allows OxyContin to be effectively administered every 12 hours." The Package Insert advises physicians that if patients suffer "breakthrough pain" near the end of their dosing interval, they should take "rescue" medications, i.e., an immediate release oxycodone product. In addition, Defendants advise that if the need for rescue medications exceeds twice a day, "it is most appropriate to increase the q12h dose, not the dosing frequency."

41. Pharmaceutical Defendants continued to stress to physicians that OxyContin should only be prescribed twice a day, and that any complaints of recurring pain should be met with increased use of rescue medications, and an increased OxyContin dosage. For example, the Pharmaceutical Defendants distributed written materials to doctors and medical providers using the acronym "TIME," which broke down as follows:

T Titrate patients every 1-2 days if necessary

I Increase the OxyContin® dose by 25% TO 50% IF NECESSARY; do not increase the dosing frequency. There is no maximum daily dosage or "ceiling" to analgesic efficacy with OxyContin®.

M Manage breakthrough pain, if necessary, with OxyIR Capsules (Oxycodone HCl immediate-release) CII at 1/4 to 1/3 of the 12-hour OxyContin® dose.

E Elevate the OxyContin® dose if more than two OxyIR rescue doses per day are required.

42. Through a patient brochure, the Pharmaceutical Defendants also directly misled patients that OxyContin would effectively manage their pain when taken just twice a day. Entitled, "A Guide to Your New Pain Medicine and How to Become A Partner Against Pain," Defendants advised patients that OxyContin is formulated to be taken every 12 hours. "This means one would probably only need to take OxyContin tablets for pain twice a day, rather than every 4 to 6 hours as is common with some other pain medications." The Pharmaceutical Defendants know that one will probably *not* find adequate analgesia when taking OxyContin alone just twice a day, and would need more than two OxyContin dosings, or rescue medication. The brochure cover shows two pill cups; clearly implying to patients that OxyContin would provide pain relief when taken twice a day for *every* patient.

43. With every advertisement, CD, video, letter, or promotional piece they produced bearing the lettering, "q12h," the Pharmaceutical Defendants maintain the misleading impression that OxyContin's "controlled-release" feature provides sufficient pain relief when taken just twice a day.

C. Misrepresenting and Failing to Warn of Risks

44. The Pharmaceutical Defendants grossly, willfully and intentionally understated and trivialized drug tolerance, dependancy and addiction throughout their marketing materials. They did so despite published reports (some of which they sponsored and/or financially supported) demonstrating substantially greater rates of tolerance, dependance, and addiction. As such, the Pharmaceutical Defendants, seeking greater profits, deliberately

exposed patients to danger.

45. Pharmaceutical Defendants misrepresented to patients, and physicians, directly and indirectly, that OxyContin presents little risk of addiction when taken as prescribed.

46. The Package Insert for OxyContin does not contain a warning about addiction in its "WARNINGS" section. Under a subheading "DRUG ABUSE AND DEPENDENCE (Addiction)," the Pharmaceutical Defendants note that OxyContin has "an abuse liability similar to morphine." However, the Pharmaceutical Defendants later undercut this vague notice in the same paragraph, stating: "Delayed absorption, as provided by OxyContin Tablets, is believed to reduce the abuse liability of a drug." The label also states, "[i]atrogenic 'addiction' to opioids legitimately used in the management of pain is very rare." The Pharmaceutical Defendants do not provide an addiction rate, do not advise doctors to ask about or consider prior abuse history, do not contraindicate OxyContin for patients with an alcohol or drug abuse history, and do not mention that some medical articles report addiction and abuse rates as high as 18.9% for patients taking narcotics outside a hospital setting.

47. The Pharmaceutical Defendants further misrepresented or omitted material facts as to the addiction risks of taking OxyContin in their patient brochure, "A Guide to your New Pain Medicine and How to Become A Partner Against Pain." That piece contains the following hypothetical question from a patient: "Aren't opioid pain medications like OxyContin Tablets 'addicting?' Even my family is concerned about this." The "response" deftly deflects the reader from a frank discussion of addiction risks:

> Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful. If you or your family have

> concerns about addiction, please talk to your doctor or another member of your healthcare team. This fear should not stand in the way of relief from your pain.

The Pharmaceutical Defendants thus created a false dichotomy between drug effects. They misrepresent to patients that so long as one takes OxyContin when in pain, one is not addicted. Addiction and a pain suffering are not mutually exclusive groups. The Pharmaceutical Defendants omit mentioning that many addicted patients take opioids not to get "high" or euphoric, but to alleviate or preempt the pain of opioid withdrawal. The Pharmaceutical Defendants repeated the aforementioned false distinction through representations made by their sales force at conferences, and in the course of detailing physicians.

48. The misrepresentation that OxyContin somehow becomes non-addictive when taken "for pain" has been repeated by the Pharmaceutical Defendants in newspaper publications. For example, Dr. J. David Haddox, a Senior Medical Director for Purdue, stated that "if you are taking OxyContin for legitimate pain, you have nothing to worry about." Instead, he suggested that OxyContin only presents a danger when snorted, chewed or injected: "If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good." Roger Alford, Associated Press, *Deadly OxyContin Abuse Expected to Spread in the U.S.*, THE CHARLESTON GAZETTE & DAILY MAIL, February 9, 2001, at P2D. OxyContin taken orally presents far greater risks than celery. The Pharmaceutical Defendants' analogy proves more callous than humorous in light of the rising number of persons hooked on, and harmed by, OxyContin, including hundreds of OxyContin related deaths.

49. Pharmaceutical Defendants also created a videotape for prescribing physicians to show to pain patients. Entitled, "From One Pain Patient to Another," the video included several purported pain patients who urge viewers to insist on opioid pain medications, and to shop for a doctor willing to prescribe opioids to them. The video failed to disclose the causes or severity of each patient-spokesperson's pain, and misrepresented the risk of addiction:

> Some patients may be afraid of taking opioids because they are perceived as too strong or addictive. But that is far from actual fact. Less than 1% of patients taking opioids actually become addicted.

50. According to the American Medical Associations's Council on Scientific Affairs, the rates of drug abuse and addiction in patients with chronic, noncancer pain have been estimated at between 3.2% and 18.9%. They further state that in multidisciplinary pain management programs, the rates of aberrant drug use have been found to be even higher. The Pharmaceutical Defendants were aware of these statistics, but omitted them from their marketing campaign. As a result, the Pharmaceutical Defendants deliberately misrepresented the addiction risks accompanying OxyContin.

51. Defendant Purdue has previously been found to have misled the public as to aspects of the efficacy and safety of OxyContin. On May 11, 2000, the FDA issued an official warning letter to Purdue ordering it to cease use of an advertisement. The ad featured a picture of an elderly woman beneath the caption, "Proven Effective in Arthritis Pain." The FDA found, among other things, that the advertisement was misleading since " . . . [T]he study [relied on for the ad] only demonstrated OxyContin 20 mg given twice daily to be significantly more effective than placebo [as opposed to 10 mg.] . . . your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is

unsubstantiated, and consequently, misleading." In addition, the FDA noted that, "the Warnings section of the PI states that 'Respiratory depression occurs most frequently in elderly or debilitated patients' . . . [that] risk is not presented in your journal ad." The advertisement also featured two pill cups, and the words "8 AM" and "8 PM" as part of Defendants campaign misrepresenting OxyContin as providing sufficient pain relief when taken just twice a day.

52. The results of the Pharmaceutical Defendants' reckless and greedy actions are many fold. First, thousands of pain patients such as Plaintiff have become addicted to OxyContin, and have suffered personal and financial ruin. These patients, like Plaintiff, face or have faced painful opioid withdrawal. They must now endure a lifelong struggle to maintain sobriety, and are at constant risk for relapse, especially if and when exposed again to opioid medications in the future. Second, there has been a notable increase in oxycodone overdoses. The Drug Abuse Warning Network (DAWN) reports the number of times a drug is mentioned in an emergency department episodes. Between 1990 and 1996, the number of episodes involving drugs that contained oxycodone remained stable. However, between 1996 (when OxyContin came on the market) and 2000, the number of episodes more than tripled. In addition to the thousands of patients who have become addicted to the drug, there are scores of individuals who have perished abusing the pills. In October of 2001, the Drug Enforcement Administration ("DEA") observed over 1,100 oxycodone related deaths, with 282 definitively labeled as "OxyContin related." As Asa Hutchinson, Administrator of the Drug Enforcement Administration, stated before Congress, the "disproportionate abuse of OxyContin is due, in part, to aggressive marketing and promotion of OxyContin by Purdue Pharma, who represented the product as having a lower abuse potential than other opiate pain relievers.

Purdue Pharma accentuated the problem by suggesting that physicians prescribe OxyContin as a substitute for a variety of less addicting existing medications." *Hearing on the Dangers of OxyContin, Before the House Appropriations Committee*, 106th Cong., December 11, 2001 (Statement of Asa Hutchinson, Administrator, Drug Enforcement Administration, United States Department of Justice).

CAUSES OF ACTION

COUNT I

STRICT PRODUCT LIABILITY

53. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

54. At all times material hereto, the Pharmaceutical Defendants, individually and collectively, have engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting OxyContin, that was defective and unreasonably dangerous to consumers including Plaintiff.

55. At all times material hereto, the OxyContin sold, distributed, supplied, manufactured and/or promoted by the Pharmaceutical Defendants, individually and collectively, was expected to reach, and did reach, prescribing physicians and consumer in the State of Alabama, including the Plaintiff, without substantial change in the condition in which they were sold.

56. At all times material hereto, the OxyContin sold, distributed, supplied, manufactured, and /or promoted by Pharmaceutical Defendants, individually and collectively, was in a defective and unreasonably dangerous condition at the time it was placed in the

stream of commerce. Such conditions include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting the Plaintiff to risks which exceeded the benefits of the drug;

b. When placed in the stream of commerce, OxyContin was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with pain management. The OxyContin manufactured and supplied by the Pharmaceutical Defendants was defective in design or formulation in that the "controlled-release" mechanism could not deliver neither steady nor sufficient amounts of oxycodone to users so as to provide effective analgesia, or to stave off painful withdrawal symptoms, thereby exacerbated the addictive nature of the drug and resulting in its risks exceeding its benefits;

c. The drug was insufficiently tested;

d. The drug was not accompanied by adequate instructions and/or warnings to fully inform the prescribing physician nor the ultimate consumer of the full nature or extent of the risks and side effects associated with their use, thereby rendering the Pharmaceutical Defendants liable to the Plaintiff;

e. The Plaintiff used the drug for its intended purpose, i.e., to manage pain;

f. The Plaintiff could not have discovered the defects in the drug through the reasonable exercise of care;

g. The aforesaid drug has not been materially altered or modified prior to its use by the Plaintiff.

57. If not for the aforementioned defective and unreasonably dangerous conditions of the drug, the Plaintiff would not have sustained their injuries stated herein.

58. As a direct and proximate result fo the defective condition of the drug, the Plaintiff have sustained serious and permanent injuries and damages including, but not limited to:

a. Drug addiction;

b. Painful drug withdrawal;

c. Depression;

d. Physical and mental pain and suffering, mental anguish, loss of capacity for the enjoyment of life;

e. Loss of the ability to earn money in the future;

WHEREFORE, Plaintiff demands judgment against the Pharmaceutical Defendants for damages, as well as all costs this action and a trial by jury. Plaintiff also demands punitive damages against the Pharmaceutical Defendants.

COUNT II

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

59. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

60. When the Pharmaceutical Defendants placed the drug into the stream of commerce, they knew of the use for which the drug was intended (pain relief, taken twice a

day, around the clock) and expressly and impliedly warranted to the Plaintiff that use of OxyContin provides consistent and sufficient pain relief when taken just twice a day, and possessed little if any risk of addiction when taken as prescribed for pain relief.

61. Plaintiff reasonably relied upon the expertise, skill, judgment and knowledge of the Pharmaceutical Defendants and upon the express and/or implied warranty that the drug was of merchantable quality and fit for use as represented by the Pharmaceutical Defendants.

62. The drug was not of merchantable quality; rather it was unsafe and unfit for their intended use, and unreasonably dangerous thereby causing injury and damage to Plaintiff.

63. As a direct and proximate result of the Pharmaceutical Defendants' breach of these warranties, Plaintiff has sustained serious and permanent injuries and damages as more specifically set forth herein.

WHEREFORE, Plaintiff demands judgment against the Pharmaceutical Defendants for damages, as well as all costs of this action and a trial by jury. Plaintiff also demands punitive damages against the Pharmaceutical Defendants.

COUNT III

NEGLIGENCE

64. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

65. The Pharmaceutical Defendants are liable to the Plaintiff for negligence in one or more of the following particulars, which negligence was a proximate cause of the harm or injuries suffered by the Plaintiff as follows:

a. In negligently and carelessly manufacturing, compounding, testing, inspecting, packaging, labeling, distributing, marketing, examining, selling, and preparing said drug in a manner that was likely to injure the user of said product.

b. By carelessly and negligently manufacturing, compounding, packaging, and distributing said product when the drug was unsafe when it reached the hands of the consuming public, including the Plaintiff herein.

c. In negligently and carelessly failing to warn and/or adequately warn the physicians of all the risks associated with the use of the said drug.

d. In negligently and recklessly failing to warn the consuming public of the unreasonably dangerous defects associated with said drug after the defendants had knowledge of the same thereby breaching the continuing duty to warn.

e. In negligently and carelessly failing to adequately test and evaluate said drug prior to placing the same into the general stream of commerce.

66. As a direct and proximate result of the negligence of the Pharmaceutical Defendants the Plaintiff sustained injuries and damages.

WHEREFORE, Plaintiff demands judgment against the Pharmaceutical Defendants for damages, as well as all costs of this action and a trial by jury. Plaintiff also demands punitive damages against the Pharmaceutical Defendants.

COUNT IV

MALICIOUS CONDUCT

67. Plaintiff restates each and every preceding allegation of this complaint and incorporates each by reference as though set forth in full herein.

68. The Pharmaceutical Defendants, directly or indirectly, maliciously and wantonly made, created, manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold OxyContin in the State of Alabama.

69. The Pharmaceutical Defendants breached their duty and were wanton and malicious in their actions, misrepresentations, and omissions toward the Plaintiff in the following ways:

a. Misled consumers as to anticipated efficacy of the drug when used just twice a day;

b. Failed to adequately and properly test the drug before placing the drug on the market;

c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, addiction;

d. Failed to adequately warn the Plaintiff of the actual likelihood of addiction upon repeated use of the drug;

e. Failed to adequately warn the Plaintiff about the nature and danger of opiate withdrawal;

f. Failed to warn the prescribing doctors that the use of the drug should be limited to those who specialized in the treatment of pain;

g. Failed to warn the Plaintiff and prescribing doctors that use of the drug should be limited to those with pain inadequately managed by less addictive methods or pain relievers, as a last resort;

h. Failed to warn the Plaintiff and prescribing doctors that the chronic use would permanently affect Plaintiff, making them tolerant to opioids and unable to achieve pain relief with anything but high doses of opioids;

i. Encouraged misuse and overuse while underplaying the side effects to doctors and the public in order to make a profit from sales;

70. The Pharmaceutical Defendants knew or should have known that the drug was unreasonably dangerous and could cause addiction. The Pharmaceutical Defendants knew or should have know that the drug caused unreasonably dangerous risks of which the Plaintiff and their prescribing physicians were misled to believe were highly unlikely, or impossible if OxyContin was taken as prescribed for a pain.

71. As a direct and proximate result of the wanton and malicious acts and omissions of the Pharmaceutical Defendants, Plaintiff has sustained serious and permanent injuries and damages.

WHEREFORE, Plaintiff demands judgment against all Pharmaceutical Defendants for damages, as well as all costs of this action and a trial by jury. Plaintiff also demands punitive damages against the Pharmaceutical Defendants.

COUNT V

FRAUD, MISREPRESENTATION AND SUPPRESSION

72. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

73. The Pharmaceutical Defendants, having undertaken the manufacturing, marketing, distributing and promoting of OxyContin were duty bound to provide the Plaintiff,

and physicians, regulators and other consumers accurate and complete information regarding OxyContin.

74. The Pharmaceutical Defendants fraudulently misrepresented to the Plaintiff that OxyContin provided smooth and sustained pain relief when taken just twice a day, and that it presented little if no risk of addiction when taken as prescribed. The continuous and ongoing course of action constituted fraud and misrepresentation.

75. The Pharmaceutical Defendants fraudulently misrepresented the facts regarding safety and usefulness of their product including, but not limited to, the following acts and/or omissions:

a. Express and implied statements

b. Publicly disseminated misinformation, including product labeling, patient brochures, medical seminar materials, promotional videos, and print advertisements

c. Misinformation provided to regulatory agencies

d. Failing to disclose important safety and risk information regarding OxyContin while having a duty to disclose to the Plaintiff and others such information.

76. OxyContin is in fact more addictive and less effective than portrayed by Pharmaceutical Defendants.

77. The Pharmaceutical Defendants fraudulently, intentionally and/or negligently misrepresented to the Plaintiff and the general public, the safety and effectiveness of OxyContin and/or fraudulently, intentionally and/or negligently concealed material including adverse information regarding the safety and effectiveness of the drug.

78. Specifically, the Pharmaceutical Defendants misrepresented to and/or actively concealed from the Plaintiff and the consuming public that:

a. The majority of users would not receive adequate pain relief taking OxyContin just twice a day;

b. Opioids like OxyContin present a much greater addiction risk to chronic users than "less than 1%" of users;

c. OxyContin presented an even greater risk for opioid withdrawal between doses, given its large amount of oxycodone, and the failure of its controlled-release feature to smoothly and sufficiently deliver the oxycodone;

d. OxyContin users were placed at greater risk for addiction given the need for frequent use of immediate release oxycodone, the failure of OxyContin to deliver smooth and sustained release of oxycodone, the potency and amount of the oxycodone used, and the Pharmaceutical Defendants instructions to physicians to maintain a bi-daily dosage regime even when the medication failed to provide adequate relief, and to simply further increase the dosage of OxyContin;

e. Until July 18, 2001, OxyContin was inappropriate as a first-line therapy for pain relief;

79. The misrepresentations of and/or active concealment alleged above were perpetuated directly and/or indirectly by Pharmaceutical Defendants acting in their individual and/or corporate capacity.

80. The Pharmaceutical Defendants knew or should have know that these representations were false and made the representations with the intent or purpose that the Plaintiff would rely on them, leading to the use of the drug by the Plaintiff.

81. At the time of the Pharmaceutical Defendants' fraudulent misrepresentations, Plaintiff was unaware of the falsity of the statements being made and believed them to be true. Plaintiff further had no knowledge of the information concealed and/or suppressed by the Pharmaceutical Defendants.

82. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which the Pharmaceutical Defendants did suppress, conceal or fail to disclose to her detriment.

83. The Pharmaceutical Defendants had a post-sale duty to warn the Plaintiff about the potential risks and complications associated with OxyContin in a timely manner.

84. The Pharmaceutical Defendants' actions constitute a deliberate action to pursue a common plan or design in commission of a tortious act in violation of Alabama law.

85. The misrepresentations of and/or active concealment by the Pharmaceutical Defendants constitute a continuing tort.

86. The Pharmaceutical Defendants made the misrepresentations and/or actively concealed this information with the intention and specific desire that the Plaintiff and the consuming public would rely on such or the absence of information in selecting the drug as treatment for pain.

87. As a direct and proximate legal result of the fraudulent acts and omissions, suppression and misrepresentations of the Pharmaceutical Defendants, the Plaintiff has

sustained serious and permanent injuries and damages as more specifically set forth herein.

WHEREFORE, Plaintiff demands judgment against the Pharmaceutical Defendants for damages, as well as all costs of this action and a trial by jury. Plaintiff also demands punitive damages against the Pharmaceutical Defendants.

COUNT X

DAMAGES

88. Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

89. As a direct and proximate result of all of the Defendants' conduct as delineated in all counts above, the Plaintiff has sustained injuries, diseases, illnesses, and/or conditions set forth above, together with pain and suffering, the past, present and future need of medical treatment, medical expenses, together with present and future disability, impairment of wage earning capacity, loss wages and a diminution in quality in enjoyment of life which includes mental anguish, fear, and severe emotional distress associated with knowing that there may be no successful treatment presently known for these diseases and illnesses. Therefore, Plaintiff is entitled to recover the maximum amount of damages from the Defendants as allowed by law.

90. In breaching their duties to the Plaintiff, as described above, the Defendants have acted intentionally, with reckless disregard for the rights of others and with gross negligence, maliciously and/or wantonly in that the Defendants knew or should have know through data available to them that OxyContin presented a far greater risk of addiction when used in the manner intended or foreseen by the Defendants, and that their aforesaid breaches

of duty would result in the injuries set forth herein and damages to the Plaintiff thus entitling the Plaintiff to recover punitive or exemplary damages for the Defendants' intentional reckless and outrageous misconduct as set forth herein.

WHEREFORE, PREMISES CONSIDERED, for all counts alleged above, the Plaintiff demands judgment against all Defendants, jointly, severally, and collectively, for the following:

a. Losses incurred as a result of Plaintiff's dependence on OxyContin, including but not limited to, past and future lost wages and expenses related to treatment for Plaintiff's dependence on and/or addiction to OxyContin.

b. Medical care and treatment related to the Plaintiff's injuries described herein, for the rest of her life.

c. Compensation for Plaintiff for:

   A. Pain and suffering, past and future;

   B. Serious bodily injury;

   C. Impairment of earning capacity;

   D. Loss of enjoyment of life.

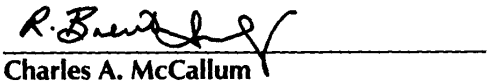
d. Punitive damages in such amount as will sufficiently punish the Defendants for their conduct in Alabama and as well as serve as an example to prevent a repetition of such conduct in this State in the future;

e. Pre-judgment interest from the date of the filing of the original Complaint;

f. Filing fees and reasonable attorneys fees and costs of this action;

g. Post-judgment interest, costs, attorney fees and such other general and further relief as may be deemed just and appropriate.

PLAINTIFF DEMANDS A TRIAL BY STRUCK JURY



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